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TITLE OF THE INVENTION (280 characters max)

ENERGY ASSISTED MEDICAL DEVICES, SYSTEMS AND METHOD

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Respectfully submitted,

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ENERGY ASSISTED MEDICAL DEVICES, SYSTEMS AND METHOD

BACKGROUND OF THE INVENTION

[0001] The present invention relates generally to energy assisted devices, systems and methods, and particularly, to energy assisted medical needles, to medical needles systems and to methods of inserting needles into tissue with the assistance of energy.

[0002] A biopsy is a medical procedure that retrieves a piece of tissue from a patient for examination by a pathologist to make or to confirm a diagnosis with a high degree of certainty. The degree of certainty in the diagnosis is dependent upon obtaining a sample of the suspect tissue that is of sufficient quality for the diagnosis to be made.

[0003] There are three types of biopsies including, surgical biopsies, endoscopic biopsies, and needle biopsies. As it is desirable to cause the patient as little pain and hardship as possible, there is a trend toward biopsies using a needle rather than a knife, toward needle biopsies using finer needles, and toward image-guided needle biopsies (to make sure that the desired tissue is biopsied). Image-guided biopsy is still in its infancy, but is growing quickly.

[0004] Imaging-guided biopsies are obtained through specially designed biopsy needles that are placed into the area of concern. Needle biopsies conducted with the assistance of imaging guidance are less invasive than a traditional surgical biopsy. Many diseases, including cancer, can be detected with blood tests or seen with X-rays, computed tomography (CT) scans, magnetic resonance (MR) and other imaging techniques. When cancer is suspected, it is necessary to obtain a sample of the abnormal tissue to confirm or rule out a diagnosis of cancer. The removal of sample tissue is called a biopsy. By examining the biopsy sample, pathologists and other experts can determine what kind of cancer is present and whether it is likely to be fast or slow growing. This information is important in deciding the best type of treatment. Traditionally, biopsy has required open surgery that requires longer recovery time and typically involves the complications of pain and scarring. With interventional radiology techniques, however, tissue samples usually can be obtained without the need for open surgery.

[0005] In a large-core needle biopsy, a special needle is used that enables the radiologist to obtain a larger biopsy sample. This technique is often used to obtain tissue samples from lumps or other abnormalities in the breast that are detected by physical examination or on mammograms or other imaging scans. Because approximately 80 percent of all breast

abnormalities are found to be non-cancerous, this technique is often preferred by women and their physicians. Breast biopsy procedure volumes are expected to increase over the next few years, likely a result of the increased convenience of noninvasive procedures.

[0006] Often biopsy procedures are uneventful. Sometime, especially with cancerous nodules, biopsy has been compared to trying to stick a cheap plastic fork into a grape in an opaque gel. In that regard, the mass tends to move out of the way unless the needle is directly on target, and the needle tends to bend if there is any attempt to adjust the path to the side. This bending is then exaggerated upon further forward motion because the cutting action of the needle is dependent upon the forward force applied. To resist the tendency to bow or buckle, needle diameter and/or wall thickness must be increased. It is normal practice for a doctor to lightly twist the needle as they insert it. In robotic biopsy procedures, the needle is inserted at a steady pace by a machine. During such steady insertion, a patient is sometimes observed to jump or rebound when the needle penetrates a particularly tough layer of tissue. This rebound or over penetration is a significant limitation to current robotic needle biopsy processes.

[0007] A significant biopsy risk in the abdomen is hemorrhage as a result of cutting a significant blood vessel as the needle is inserted. Bleeding complications occur most often with liver biopsy, especially when the lesion is superficial and not covered by normal liver tissue. Other complications, such as infection, are very uncommon despite the fact that the needle will occasionally traverse the bowel. In a chest biopsy, pneumothorax (air in the space between the lung and the rib cage) is the most common complication, occurring in about 25% of patients. In addition, there are a number of lesions near the rib cage that cannot be accessed with straight biopsy needles. A few fatalities from lung biopsy have occurred from puncturing an adjacent pulmonary vein. In many parts of the body, there is a risk of severing nerves. In the facial area this can lead to permanent paralysis and disfigurement.

[0008] Biopsying hard tissue or through hard tissue (to, for example, biopsy bone or the bone marrow) is especially difficult because of the stiffness of hard tissue. Bone biopsy needles must be especially strong, and thus typically have thicker walls than biopsy needles used with soft tissue and larger diameters than biopsy needle for use with soft tissue. Bone biopsy needles also typically have large T-shaped handles to exert considerable forward force upon the needle.

[0009] The challenges discussed above in relation to biopsy also occur with needle aspiration or drainage procedures. Aspiration and drainage techniques are used to collect or remove tissue or fluid from the targeted anatomy. Similar to a biopsy, a fine needle aspiration can be used to withdraw cells from a suspected cancer. It also can diagnose fluids that have

collected in the body. Sometimes, these fluid collections also may be drained through a catheter, such as when pockets of infection are diagnosed.

[0010] Needles are also used in procedures other than biopsies and aspirations. For example, needles are used to gain access to a patient's vein for the infusion of fluids or drugs. The difficulty in gaining access to a patient's vein include piercing the tough vein wall, with the vein having the tendency to move from side to side, and potentially piercing through the back side of the vein.

[0011] Needles are also used to administer drugs subcutaneously. Especially for conditions that require multiple injections over time, such as diabetes, the smaller the needle, the less the damage to tissue and the less the pain. Also, diabetics use needles to cut the skin so a blood sample can be taken. Again, a smaller cut with the option of withdrawing blood through the needle could be beneficial.

[0012] Needles can also be inserted into the liver or other internal organs for the delivery of chemo therapy or chemo ablation. Needle electrodes are also commonly used for RF or cryo tissue ablation.

[0013] Moreover, needles are inserted into tissue to measure electrical signals from the tissue. Needles with sensors can likewise be used to measure other properties of tissue, for example, temperature, pressure, elastic properties, electrical conductivity, dielectric properties or optical properties.

[0014] Abscess drainage procedures involve the placement of drainage catheters into an abscess, guided by imaging techniques. The abscess is drained to prevent advanced infection of the localized tissue and organs. Biliary drainage procedures are generally used to relieve an obstruction to the biliary ductal system of the liver by placing a drainage catheter or stent through the patient's side and into the liver. Nephrostomy placement is the positioning of a catheter into the patient's kidney from the back. This is usually done to relieve an obstruction to the flow of urine from a tumor or some other source. A nephrostomy can be placed to allow access for removal of kidney stones, laser therapy of urothelial tumors, and the removal/dilation/stenting of strictures.

[0015] Gastrostomy placement involves the positioning of a feeding tube directly through the abdominal wall and into the stomach under x-ray guidance. It shares some of the difficulties discussed above including bleeding and difficulty cutting through tissue fascia. It is generally done for patients who will need long-term nutritional support and are not capable of maintaining their own nutritional needs orally, often for reasons such as neurological impairment, mental

disorders, or severe esophageal disease including carcinoma. Gastrostomy tubes may be placed surgically, endoscopically or percutaneously.

[0016] Needles are also used to make fluid connections, for example to penetrate rubber stoppers, for removal of a drug from or insertion of a drug into a container. Needles are also used to make fluid path connections. One of the challenges in these uses of needles is to avoid coring, that is cutting a plug from the rubber stopper or other material that then lodges in the open lumen of the needle.

[0017] In all the uses describe above, accidental needle stick injuries are a serious hazard for health care workers and patients. There are many devices for rendering a sharp needle safer by covering the tip in one of many ways. Most require some action on the part of the health care worker to activate the protection mechanism. Often this action is forgotten or improperly executed, resulting in injury.

[0018] In the field of biopsy needles, single shot spring-loaded biopsy devices have been developed in an attempt to overcome or reduce the effect of a few of the challenges set forth above. Spring-loaded biopsy needles are inserted manually to the target tissue, and the actual biopsy is taken by actuation of a single-shot spring mechanism. There are a number of devices employing this principle on the market.

[0019] In a number of medical instruments, energy other than manual energy has been applied to effect tissue cutting, emulisification, cauterization etc. For example, an energy (that is, ultrasonic energy) assisted surgery devices exist such as the ULTRASONIC HARMONIC SCALPEL® available from Ethicon Endo-Surgery, Inc. of Cincinnati, Ohio. The energy assisted scalpel uses various levels of ultrasonic energy to cut and/or coagulate tissue, primarily during endoscopic procedure.

[0020] US Patent No. 6,514,267 also discloses an ultrasonic scalpel. It is indicated that the ultrasonic scalpel appears to transmit the ultrasonic energy more rapidly to the tissue if the scalper is relatively blunt, rather than ultrasharp. Another ultrasonic scalpel is disclosed in US Patent No. 6,379,371.

[0021] Ultrasonic energy has also been used in an instrument use to "liquefy" the lens of the eye for removal during cataract surgery. An example of such a device is disclosed in US Patent Nos. 6,352,519, 6,361,520 and 4,908,045. Although energy other than manual energy (such as ultrasonic energy) has been applied to various medical instruments as discussed above, there has little progress in developing an energy assisted medical needle. It is thus desirable to develop energy assisted medical needles, systems including such needles and methods of

inserting needles using energy assistance to reduce or even eliminate some of the problems associated with the insertion of needles into tissue. Moreover, it is desirable to develop improved energy assisted medical devices generally.

SUMMARY OF THE INVENTION

[0022] In one aspect, the present invention provides a device for penetrating tissue and removing a biological sample. The device includes a biological sampling element to remove a biological sample. The biological sampling element includes a passage therethrough. The device further includes a penetrator positioned within the passage. The penetrator is energized in a repetitive manner to assist in penetrating tissue. The biological sample element can be adapted to remove a tissue sample or a biological fluid sample (for example, blood).

[0023] As used herein in connection with effectors of the present invention, the terms "energized" or "apparatus energized" refers to the application of energy (for example, mechanical energy or thermal energy), other than by direct manual manipulation, to a penetrator (or one or more effectors thereof) of a device of the present invention such that the penetrating capability of the device is at least partially decoupled from or, in other words, not directly proportional to the forward force applied to the effector. Typically, electrical energy or stored mechanical energy is used in energizing the devices of the present invention. As used herein, the term "penetrate" refers generally to passing into or through tissue (including both soft tissue and hard tissue) through any action including, for example, cutting, cleaving, severing, ripping, emulsifying, liquefying, or ablating.

[0024] In one embodiment, the penetrator is energized continuously to assist in penetrating tissue. Alternatively, the penetrator can be energized for discrete periods of time. The penetrator can be energized in a manner to cause motion of the penetrator. In addition or alternatively, the penetrator can be energized to cause heating of the penetrator.

[0025] The motion of the penetrator includes at least one of rotational motion, lateral motion or axial motion. In several embodiments, the penetrator includes at least a single effector that is moved. The penetrator can include a plurality of effectors, at least one of which is moved. In one embodiment, the penetrator includes at least two effectors in close proximity to each other. Relative motion between the two effectors assists penetration of tissue via interaction with tissue in regions where there is close proximity of tissue to an interface between the two effectors. In another embodiment, the penetrator includes at least two effectors, a first effector which is moved

and a second effector in close proximity to the first effector which is stationary. The first effector and the second effector cooperate to penetrate tissue via interaction with tissue in regions where there is close proximity of tissue to an interface between the first effector and the second effector. In a further embodiment, the penetrator includes at least two effectors, a first effector which is moved and a second effector in close proximity to the first effector which is also moved. Once again, the first effector and the second effector cooperate to penetrate tissue via interaction with tissue in regions where there is close proximity of tissue to an interface between the first effector and the second effector. As used herein with reference to effectors of the present invention, the phrases "in proximity" or "in close proximity" refer generally to a first effector, which can be moving or stationary, being close enough to a second effector, which is moving, such that the presence of the first effector affects the interaction with tissue of the movement of the second effector.

[0026] In one embodiment of the present invention, the biological sampling element includes a first tubular structure and a vibrational coupler that couples rotational energy into the first tubular structure such that the vibrational energy cuts tissue at the leading edge of the first tubular structure. The biological sampling element further includes a second tubular structure inside the first tubular structure such that the cut tissue inside the second tubular structure is protected from the effect of the rotational energy of the first tubular structure. The penetrator passes through the second tubular structure.

[0027] In another aspect the present invention provides a device for penetrating tissue and positioning a catheter, including a catheter comprising a passage therethrough; and a penetrator in operative connection with the catheter. The penetrator is energized in a repetitive manner to assist in penetrating tissue. In one embodiment, the penetrator is removably positioned within the passage of the catheter. In another embodiment, the penetrator is positioned on the exterior of the catheter. As used herein, the terms "catheter" or "cannula" refers generally to a tubular medical device for insertion into canals, vessels, passageways, or body cavities, for example, to permit injection or withdrawal of fluids or to keep a passage open.

[0028] In a further aspect, the present invention provides a needle for penetrating tissue including a first effector comprising a surface and a second effector comprising a surface. The surface of the second effector is in close proximity to the surface of the first effector. The device further includes at least one actuator in operative connection with one of the first effector and the second effector. The actuator is adapted to cause relative motion between the first effector and

the second effectors such that tissue penetration takes place in regions where there is close proximity of tissue to an interface between the first effector and the second effector.

[0029] In another aspect, the present invention provides a needle for sampling tissue including a first tubular structure and a vibrational coupler that couples rotational energy into the first tubular structure. The vibrational energy is suitable to penetrate tissue at the leading edge of the first tubular structure. The device further includes a second tubular structure positioned inside the first tubular structure, such that cut tissue passes into the second tubular structure and is protected from the effect of the rotational energy of the first tubular structure.

[0030] In still another aspect, the present invention provides a needle for penetrating tissue including a first effector in proximity to the distal end of the needle; and at least one actuator in operative connection with the first effector to energize the first effector to assist in penetrating tissue.

[0031] In another aspect, the present invention provides a needle system including a needle in operative connection with a syringe and an actuator in operative connection with the needle. The actuator is adapted to energize to the needle to assist in penetrating tissue. The needle can, for example, be connected to the syringe by a hub, wherein the hub allows relative motion between the needle and the syringe. The needle and the syringe can both be energized. In one embodiment, the actuator is in operative connection with a cradle in which a needle and syringe are insertable to energize the needle.

[0032] In another aspect, the present invention provides a method of inserting a needle into tissue, including the step of energizing at least a forward end of the needle to assist in penetrating tissue.

[0033] In still a further embodiment, the present invention provides method of inserting a catheter into tissue, including the step of energizing an effector positioned at a forward end of the a catheter insertion device to assist in penetrating tissue.

[0034] In general, the energy assisted devices and systems of the present invention can be used in practically any medical procedure requiring penetration, hole boring or incision of tissue including, for example, biopsies of both soft and hard internal tissue; removal of tissue for therapy (for example, cataract removal); cauterization, incision (that is, surgery), needle access to veins, blood testing (including small sample blood testing as, for example, practiced by diabetics) aspiration, drainage access, gastrostonomy, chemical or RF ablation, sensor access to tissue and drug delivery to target tissue. Several advantages are provided over common instruments (including needles) currently used in such procedures. In general, these advantage are afforded

by at least partially decoupling the penetrating or cutting action of the devices of the present invention from the forward force applied thereto. For example, smaller needles can be used, less push force is require, less "tug" force is felt by the patient, there is less of a tendency of deflection from the desired path, a curved path can be followed, the path can be changed during insertion, and there is less bleeding and damage to tissue. Patient pain can further be reduced with the devices of the present invention by, for example, local injection of an anesthetic, local affecting of nerves via applied electrical energy, local affecting of nerves via applied vibrational energy, air exclusion and/or the tissue penetrating profile of the device.

BRIEF DESCRIPTION OF THE DRAWINGS

[0035] Other aspects of the invention and their advantages will be discerned from the following detailed description when read in connection with the accompanying drawings, in which:

[0036] Figure 1 illustrates a block diagram of one embodiment of an energy assisted needle system of the present invention.

[0037] Figure 2 is a cross-sectional illustration of one embodiment of the patient end of an energy assisted needle.

[0038] Figure 3 is an illustration of another embodiment of the patient end of an energy assisted needle.

[0039] Figure 4 is an illustration of a further embodiment of the patient end of an energy assisted needle using axial motion for penetration.

[0040] Figure 5 is an illustration of the patient end of any of the energy assisted needles of Figures 2, 3 or 4 with the center penetrating assembly removed so that a sample of tissue can be taken.

[0041] Figure 6 is an end on or top view of the actuator end of the energy assisted needle including a mechanism to couple rotational motion to the effectors.

[0042] Figure 7 is an illustration of the actuator end of the energy assisted needle including a mechanism to transform longitudinal motion into rotational motion of the effectors.

[0043] Figure 8 is an illustration of one embodiment of an energy assisted needle system including a disposable needle.

DETAILED DESCRIPTION OF THE INVENTION

[0044] The energy assisted systems of the present invention can be used in connection with a number of medical devices and/or procedures. However, the systems of the present invention are discussed primarily herein in connection with representative embodiments of energy assisted "needles". Figure 1, for example, illustrates a block diagram of an energy assisted needle system of the present invention that will be used to discuss the general functionality of various embodiments of energy assisted needles of the present invention. As used herein, the term "needle" refers to relatively slender instruments that can be used to penetrate, and includes instruments having a passage or channel for introducing material into or removing material from the body parenterally.

[0045] In system 10, power or energy is provided by a power source 11. A number of different types of energy can be used in the systems of the present invention. Electrical energy can be provided from batteries, fuel cells, line power, or similar devices. Mechanical energy can be provided by compressed air, hydraulics, or spring power.

[0046] The power or energy is controlled through a power controller 11 such that one or more actuators, 21a, 21b, ... 21n, create actions or motions. For example, mechanical actions or motion can be created from electrical power by any of many electromechanical elements, for example solenoids, motors (including, for example, linkages or cams), piezoelectric elements, ultrasound transducers, electroactive actuators (for example, shape memory alloys such as nitinol, electroactive polymers, and electroactive ceramics), magnetostrictive elements, and electrostrictive elements. Hydraulic elements and pneumatic elements and also be used to create mechanical actions. Likewise, thermal energy can be used in the form of, for example, heat/shock from electrical elements and lasers can create photon energy.

[0047] These actuators 21a, 22b ... 21n act upon one or more effectors 31a, 3b ... 31n which transmit the effect, the energy, to the patient 99, achieving the medical goal of the user 60. Effectors 31a, 31b ... 31n are preferably associated with each other or held together by an interface 52 which can be used to position and move effectors 31a, 31b ... 31n. In Figure 1, interface 52 is shown diagrammatically as a box and an oval encompassing effectors 31a, 31b ... 31n.

[0048] User interface 52 can for example be a hand-held interface. Alternatively, user interface 52 can be part of a robotic or automated interface. The control of interface 52 can be partially or fully automated. As described below, feedback can be provided to user interface 52

to assist in control thereof. Guidance of user interface 52 can be manual, machine assisted, or fully machine controlled (such as robotic biopsy). As known in the art, various imaging systems can be used to facilitate guidance of interface 52 (and thereby effectors 31a, 31b ... 31n. For example, ultrasound imaging, X-ray imaging, CT imaging, and/or MR imaging can be used in connection with either manual or machine assisted guidance. There are a number of systems that provide some type of feedback for guidance. For example, an image of the needle tip and the target tissue can be provided so that the doctor can make sure the needle is heading to the right tissue, is avoiding any tissue that could be damaged, and samples the target tissue with confidence. Various other systems use images to calculate a needle path and then have a mechanism such as angle guides or laser guides to help make sure the doctor places the needle at the proper angle and goes to the correct depth. In the MAMMATOME® Breast Biopsy System available from Ethicon Endo-Surgery, a coordinate system directs the biopsy needle to the proper location. Tremor cancellation devices are being built to assist with surgery. Such devices may also be applied to improve biopsy procedures.

[0049] One or more sensors 41a ... 41n can be associated with any of the effectors 31a, 31b ... 31n , actuators 21a, 21b ... 21n, the patient 99, or any of the other system components. The sensors communicate with a sensor interface 50 so that information can be given to the user 60 or other equipment for monitoring, controlling, or other functions. The sensor information can also be fed to the power controller to provide feedback control. Sensors 41a ... 41n can, for example, sense tissue properties (for example, water content, fat content or other properties). Sensors can, for example, include durometers, conductivity sensors, dielectric property sensors, optical sensors, strain gauges, ultrasound reflectance sensors and microelectromechanical-system (MEMS) sensors.

[0050] Sensors can also be used to provide, for example, audible or tactile feedback to the user. For example, sensors (such as strain gauges and/or other sensors) on effectors 31a, 31b ... 31n can sense resistance to motion, forward motion, bending, friction and/or temperature to provide feedback to the user. This feedback can, for example, alert the user to undesired bending or path deviation. Such feedback can also indicate desired conditions, such as penetration of a vein wall or penetration into bone marrow.

[0051] The sensors may also provide diagnostic information. In some cases the sole purpose of placing the needle in the tissue may be to make a measurement via the sensor.

[0052] Sensor interface 50 can communicate with the power controller, which can modulate the power applied to one or more actuators based upon the information of one or more

sensors. And example of this is to provide an effect similar to power steering or power brakes, such that when a sensor 41a, 41b, ... 41n senses an increased force resisting forward motion, the power to the appropriate actuator can be increased to increase the cutting action and thus reduce the resistance to forward motion to its desired level. Cutting action can also be quickly reduced when reduced forward resistance is encountered.

[0053] The user can directly interface through user interface to the power controller, for example, to control cutting level or simply to turn the cutting action on when the needle is use or to turn the cutting action off when the needle is not in use, thereby making the needle inherently less of a needle stick risk. The arrows between the system blocks of Figure 1 represent transmission of energy, information, control, or communications.

[0054] In general, motion is applied to one or more effectors 31a, 31b ... 32n via actuators 21a, 21b .... 21n, respectively. Many different types of motion can be applied to effectors 31a, 31b ... 31n. Moreover, the type of motion applied to one or more different effectors can be different. In general, the motion applied is preferably repetitive. The motion can be applied continuously or for discrete periods of time. Example of types of motion applicable to effectors 31a, 31b ... 31n include, but are not limited to rotation (for example, unidirectional, reciprocating, random, hammer drilling etc.), linear motion either axially or perpendicular to the needle axis (for example, oscillatory, random, impulse transmitted and hammering), arbitrary directional motion and combined motion. Combined motions can be as simple as rotational motion about the axis and reciprocal motion along the axis. Or it can be as complicated as a geological tunnel boring action where, for example, there is overall rotation and there is rotation of many cutter elements within the overall rotation. Effectors can act in coordination as in two cooperating moving surfaces. Effectors can also act in cooperation with a stationary surface.

[0055] The gross motion(s) or path of the needle can follow a curve (including arbitrary curves and complex curves). Following a curve can, for example, be advantageous in biopsies in which obstacles (for example, ribs) are to be avoided.

[0056] In general, motions applied to effectors 31a, 31b ... 31n of the present invention can vary in rate, frequency, amplitude and duration/timing of application. The frequency of oscillatory motions can vary over a wide range. For example, the frequency can be less than 1 Hz. Likewise, the frequency can be in the range of approximately 1 to 10 Hz. The frequency further can be in the range of approximately 10 to 1000 Hz, in the range or approximately 1 kHz to 10 kHz, in the range of 20 kHz to 2 MHz or greater than 2 MHz. At higher frequencies, the amplitude of the motion is limited as a result of the acceleration required to reverse the direction.

In the case with combinational motion, it is preferred that the motions be of the same frequency, of harmonics of each other, of slightly different frequencies, or of significantly different frequencies. Examples will be given later

[0057] The structure of effectors 31a, 31b ... 31n can be varied. For example, the forward surface(s) or tip(s) of effectors 31a, 31b ... 31n can be sharp or pointed (including, for example, a single or multiple bevels). The surfaces can also be rounded or blunt. The surfaces can further be smooth or rough on, for example, a micron scale or a tens of micron scale. Likewise, a variety of action surfaces can be provided. For example, in the case of a single action surface, the surface can be spiral as in a corkscrew. A rotating scoop-like surface can also be used. In the case of a single action surface, a second surface can be provided as an action stop or shield. In the case of action between two surfaces, the surfaces can cooperate as in a cutter and anvil, an electric knife or as in opposing "Pac Man" jaws. The two surfaces can act in a coordinated fashion or independently. Multiple thrusting elements (which are activated for example, similarly to the wires used in dot matrix printers – see, for example, U.S. Patent No. 4,802,781, the disclosure of which is incorporated herein by reference) can be provided which operate in tandem and/or sequentially. Additionally, force can be applied through application of fluid jets or through a vacuum (wherein, for example, tissue is pulled against a surface).

[0058] The cross-sectional shape of effectors 31a, 31b ... 31n can vary widely. For example, the effectors can be conformed to be rotationally symmetric, to be a rectangular shape or a thin straight line, to be multiple lines initiating from a center, to be multi pointed (star patterns) or to lack symmetry. These shapes may be chosen to provide the desired cut pattern or cross section.

[0059] The effectors can be straight and rigid over the length thereof or be rigid and curved. It is preferred that one effector provide the primary shape and that the other effectors be relatively flexible and thus able to conform to the shape of the rigid effector. Moreover, flexibility can be provided. Preferably such flexibility can be controlled or steered by the user by, for example, methods similar to those currently used in connection with steerable laparoscopic devices or steerable catheter devices..

[0060] Because effectors move with respect to each other, there needs to be limited friction between them. This requires sufficient tolerances to ensure clearance between adjacent effectors. Surface treatments such as Teflon or "hard coating" can be used. Surface treatments can be used to increase smoothness and thus reduce friction. Or, materials can be chosen to

provide inherent lubricity, such as a smooth metal mated with high-density polyethylene. Liquid lubricants such as silicone oil can be inserted between effectors in manufacture. A liquid for lubrication, such as physiological saline, can be injected between effectors during use.

[0061] Because the cutting effort has generally been separated from forward force, the effector materials can be expanded beyond the traditional needle material of stainless steel or other metals. Consider a paper cut; energy in the form of relative motion allows a very weak and flimsy material to make a quick incision. While paper is not stable in a moist environment, thin plastics or ceramics may be used for effectors. Especially plastics loaded with abrasive particles could be beneficial if the abrasives can be exposed on the patient end by melting, grinding, solvents, or other means. And, if metals are used, very thin metal effectors are advantageous.

[0062] Figure 2 illustrates one embodiment of an energy assisted needle that can be used in the system of Figure 1. In that regard, Figure 2 illustrates a patient end 100 of an embodiment of the energy assisted needle. The energy assisted needle includes a central core or shaft, often called a stylet 101 that is generally pointed and can have a rough surface abrasive, similar to a very fine file. Coring tubes 102 and 103 are generally concentric with core 101. Sheath 104 is generally concentric with all of these. Elements 101, 102, 103, and 104 are referred to by the general term "effectors' because they effect (or prevent an effect on) the tissue in one way or another or at one time or another. There are four effectors in the embodiment of Figure 2.

[0063] To penetrate tissue, stylet 101 is moved or agitated. This agitation can, for example, be unidirectional rotation at a rate that does not cause significant heating. Likewise, the agitation can be a reciprocal motion, rotationally and/or axially, similar to the operation of a jackhammer. The rough surface of stylet 101 abrades and tears the tissue so penetration is easier than without energy assistance. As described above, other motions or combination of motions can be used. The rough surface of stylet 101 can be randomly rough, or it could have a spiraled pattern of groves and edges that tends to separate tissue along fascia.

[0064] Clearance channel 106 between core 101 and effectors 102, clearance channel 107 between effectors 102 and 103, and clearance channel 108 between effectors 103 and 104 can be used to deliver or remove fluids such as saline, coolant, local anesthetics, and disinfectants to or from the cutting areas. Channels 106, 107, and 108 also provide separation or clearance between effectors 101, 102, 103, and 104, should distinct motions be desired.

[0065] With stylet 101 in place and energy applied, the needle penetrates into tissue or other material without cutting a core or a sample. Tissue is just stretched and moved out of the way. Examples of suitable actuators for this embodiment are discussed below.

[0066] Figure 3 shows an alternative embodiment of an energy assisted needle with two effectors 121 and 122 forming the stylet. The actuators are powered so that there is relative motion between effectors 121 and 122. For example they can both rotate, either in opposite directions or in the same direction with different speeds. Alternatively, one effector can remain still and the second effector be moved. In Figure 3, effector 121 is shown as having two different parts on the patient end. The axis of symmetry the tip 121a is slightly different than the axis of rotation of the main shaft 121b. Thus, as effector 121 is rotated, the tip segment 121a moves closer to and away from the tip of effector 122. This motion can provide the benefit of "teasing" apart tissue along fascia. This teasing action reduces the tendency to cut significant blood vessels or nerve bundles. Effector 121 can alternatively be appropriately sized and effector 122 can be appropriately sharpened so that there is cutting action only at the very tip, or along surface 122a, or along surfaces 122a and 122b, which effectively cuts a line through the tissue being penetrated. Examples of actuators for this embodiment are also discussed below.

[0067] Figure 4 shows another embodiment of a stylet including two effectors 141 and 142. These effectors have small serrations on the tip, similar to those on the biting parts of a deer fly or the serrations on an electric carving knife or saber saw blades. The preferred motion for effectors 141 and 142 is axial motion, with impulses alternatively being applied to effectors 141 and 142. As one of the effectors is thrust forward, it pushes the other sideways into the tissue, holding the whole needle in place and reducing backsliding of the whole needle assembly. Examples of suitable actuators for this embodiment are also discussed below.

[0068] Figure 5 shows a cross-sectional view of the patient end of an energy assisted needle 150 with the stylet removed. In this configuration, needle 150 is ready to take a tissue sample. In one embodiment, there is relative motion between effector 102 and effector 103. This motion can be continuous rotational motion, intermittent rotational motion, reversing rotational motion, or any of these in combination with axial motion. A cutting action between the edges of effectors 102 and 103 results. The edges of effectors 102 and 103 can be intentionally macroscopically serrated, or they can be ground with a bevel, that on the microscopic level will tend to have serrations as a result of the roughness of the grinding process. In either case these serrations enhance the cutting action. Because the cutting action is a result of the relative motion of the two surfaces, and not a result of the axial force exerted, the benefits of the energy assisted needle described above can be realized.

[0069] To allow for axial length tolerances, there can be relative axial motion as well as rotational relative motion. The frequency of axial motion can, for example, be an order of

magnitude slower than the frequency of rotational motion. Another method of accommodating axial tolerances is to have the bottom edge of effectors 102 and 103 have a macroscopic bevel or wave configuration, so that the relative rotational motion ensures that there is a cutting action over the whole circumference. A further strategy to minimize axial tolerances includes assembling the needle effectors and then grinding the forward ends of the effectors while they are assembled using opposing grinding surfaces (either sequentially or simultaneously) so that a bevel is ground from both sides and meets at the junction of the two effectors.

[0070] Figure 6 shows an end on view of the energy assisted needle of Figure 5. Effector 104 is coupled to gear 164 on the underside or opposite side from this view. Similarly effector 103 is coupled to gear 163 and effector 102 is coupled to gear 162. Hole 161 provides a passage through which a stylet or stylet assembly can be inserted. The stylet (not shown) can also have a gear (not shown) that can be used to couple motion to it. Gear 162 is rotated by gear 172 that is connected to an actuator that can, for example, be an electric motor, rotary solenoid, air motor, or other rotary device. Similarly gear 163 is coupled to gear 173 and thus to a rotary actuator. In one embodiment tube 104 is a sheath that does not rotate, however in some situations such as with a curved needle, it could be beneficial to rotate the sheath for directional control, so gear 164 is shown coupled to gear 174 which can be actuated if beneficial. The motor or rotary actuator can apply continuous, intermittent, oscillator, or arbitrary rotary motion as desired. Other arrangements of gear size and gear placement are possible if needed for packaging optimization. For example, if it is desirable to pull out effectors 102 and 103, for example to remove a tissue sample, the "gear tree" can be constructed with the top gear being the largest gear and the bottom being the smallest.

[0071] To allow for axial motion, the planes of meshing gears can be separated by spring elements, for example wave springs, leaf springs, or elastomeric washers. These spring elements allow relative axial motion while rotational motion is occurring. Linear actuators of various types can be used.

[0072] Motors and similar actuators are relatively low speed, although high amplitude actuators. Motors can, for example, operate at 7200RPM. Some can operate above 10,000 RPM. To get faster motion, especially reciprocal motion, the arrangement of Figure 7 can be utilized.

[0073] In that regard, Figure 7 is a cross-sectional view of an alternative embodiment for the actuator end of the needle of Figure 5. The tube that is effector 104 is squeezed between a flat surface 204b and a surface with a vertical V-groove 304v. This V-groove defines a position for the outer effector 104. Effector 103 is gripped between two flat surfaces 203a and 203b of an

actuator 203, and effector 102 is gripped between flat surfaces 202a and 202b of an actuator 202. The surfaces 204b, 204v, 203b, and 202b are all rigidly connected together. The surfaces 202a and 203a are moved in an oscillatory in a direction perpendicular to the plane of the diagram. This motion causes elements 103 and 102 to rotate in opposite directions. This motion can, for example, be created by an ultrasonic transducer and horn arrangement with the axis of motion perpendicular to the plane of this drawing. The transducer and horn can, for example, move from 50 to 100 microns at 55 kHz, depending upon the power level supplied. Thus there is 100 to 200 microns of relative motion between the two edges of effectors 102 and 103 in Figure 5, provided there is no significant attenuation or resonance at that frequency. Resonance can be employed to significantly increase the amplitude of motion. A linear motion of actuator elements 202 and 203 can also be created by other electromechanical means, for example solenoids, cams, and electronically excited vibrating springs that act on the actuator arms 202a and 202b and or 203a and 203b in a plane parallel to and distinct from the plane of Figure 7. The remainder of the elements can, for example, be arranged similarly to that of the elements of ultrasonic scalpels disclosed in US patents 6,514, 267 and 6,379,371 which are incorporated herein by reference.

[0074] While, in one preferred embodiment, both effectors 102 and 103 are moved, it is also possible to move only one of these effectors. For example, if only effector103 is moved, then the ultrasound energy input to effector 103 could be sufficient that the tissue is cauterized as it is cut. This has the benefit of minimizing bleeding and seeding of any cancerous cells down the needle track as the needle is removed. By not rotating the inner effector 102, the cut tissue sample is collected in effector 102 and is protected from the movement of effector 103. This minimizes the damage to the tissue sample and maximizes its diagnostic value.

[0075] The needle can also be operated to switch between the two modes of action described above. The initial cutting can result from the relative motion of the serrations on the edges of effector 102 and 103. The effector 102 can then be stopped and effector 103 excited with sufficiently increased energy to separate the tissue sample from the remainder of the patient and cauterize the end of the sampling volume.

[0076] Alternative methods for separating the tissue core or plug at the end of the sampling include manually provide gross sideways or lateral motion of the needle tip while the cutting energy is still being applied. Alternatively, a corkscrew or spring like element can be inserted in the center lumen to capture and pull out the tissue sample. Furthermore, an energizable wire can be placed across a forward end of the needle tip, and the wire can be

energized to separate the tissue. U.S. Patent No. 6,387,057 disclosed use of a cutting wire on the distal or forward end tissue removing device to assist in separating a tissue core or plug.

[0077] There are a number of reciprocating actuators that can provide the linear reciprocation to operate stylet effectors 141 and 142 in Figure 4. In one embodiment solenoids similar to those used in dot matrix pin printers are used. Examples of such solenoids are described in US Patent Nos. 4,802,781 and 4,840,501, which are incorporated herein by reference. The solenoid driven pins can be mechanically coupled to the effectors 141 and 142 through friction fitting sleeves, or by other suitably rigid means. Alternatively, the pins of the actuators can end in cups which fit over the ends of effectors 141 and 142 such that only a pushing force can be applied by an actuator pin to effector 141 or 142. The force to hold the effectors 141 and 142 against the actuator pins is provided by the tissue resistance to forward motion. Alternatively, springs can be incorporated to push effectors 141 and 142 against the actuator pins. Alternatively, the actuators could be manufactured as a single piece with the effector. For example, the effector could be partially or totally made from nitinol that changes shape with temperature. The needle of the design of Figure 4 could be advantageously applied to getting a small blood sample for blood glucose testing.

[0078] In addition to the flat saw-blade-like effectors 141 and 142, more rounded effectors can be used with the axial motion described above. The effectors can, for example, be pie-shaped in cross section to better fill the tube. There could be more than 2 effectors. The outside of one or more effectors can be serrated or barbed to allow easy forward motion and to resist reverse motion.

[0079] Figure 8 shows another embodiment of an energy assisted needle 320. In this case, disposable needle 320 has a hollow shaft 322 connected to a hub 321. Hub 321 has a female luer lock that can be tightly attached to syringe 300 by twisting it on to a male luer connection 311. This configuration makes the syringe and needle one relatively rigid body and prevents leakage of fluid from the joint between the needle and the syringe. The fluid in the syringe and the syringe plunger for loading and expelling fluid are not show for simplicity.

[0080] By applying an energy assist to needle 320, it can penetrate the skin more easily and thus the forward thrust force is reduced (or even eliminated). This energy assistance allows a smaller diameter needle to be used, reducing the pain and tissue damage. Needles of the present invention can, for example, have a diameter of 0.25 inches or less. Indeed, needles of the present invention can have a diameter of 0.1 inches, 0.01 inches or less. This is of great benefit, for

example, to patients who require frequent and long-term injections of medications, such as insulin dependent diabetics.

[0081] Syringe 300 and attached needle 320 are mounted in an energizer 330. The energizer 330 includes an actuator 332 that grips shaft 322 of needle 320. The gripping connection can be a friction grip similar to that discussed in connection with Figure 7.

[0082] Actuator 332 can, for example, be a piezoelectric stack that operates as described in connection with Figure 7. The user interface to power controller 51 in this case is a button 333. When the user activates/pushes button 333, an internal switch is closed. In this case, the switch is power controller 12 that allows power to go from power source 11 (for example, a battery) to a drive circuit, both or which can be contained in housing 331, which energizes the piezoelectric elements in actuator 332.

[0083] In an alternative embodiment, needle shaft 322 can have an adapter attached to it to facilitate the coupling to actuator 332. For example, concentric gears can be provided as described in connection with Figure 6. In that case, actuator 332 can be a mating gear connected to a motor in housing 331, which is energized by switch 333.

[0084] In one embodiment, actuator 332 provides rotational motion to the needle shaft 322. Actuator 332 can also provide axial motion or both rotational and axial motion. Preferably, lateral motion is sufficiently small to prevent needle shaft 322 from buckling as it is being inserted into the patient.

[0085] In one embodiment, actuator 332 preferably mounted ¼ of a wavelength from the hub 321 at the frequency used. Needle tip 323 can be positioned n/2 wavelengths from the actuator 332. This configuration assists in ensuring that the movement at hub 321 is minimized and the movement at the needle tip is maximized. The wavelength is a function of needle shaft 322 material properties and dimensions. If it not convenient or desirable to have this spacing, then instead of the rigid adhesive connection between shaft 322 and hub 321, a thicker section of a more flexible adhesive, such as silicone could be employed. Such a flexible adhesive or other coupling accommodates the rotation (and/or other motion) of needle shaft 322 without causing significant rotation of hub 321.

[0086] In an alternative embodiment, actuator 332 energizes both needle 320 and syringe 300. Because the mass being energized is significantly higher, it is likely that lower frequency motions will be desirable. This embodiment has the benefit of allowing commonly available syringes and needles to be used. However, there still can be a benefit to having a custom locking shape. For example, the hub can have gear teeth on the outer surface, to match

with a gear in the actuator. Or, the syringe luer 311 could have flat elements to better mate with flat elements on the actuator and provide more positive energy transfer.

[0087] For simplicity, needle shaft 322 may be a single effector. Alternatively, the needle shaft may utilize several effectors in any of the arrangements discussed above.

[0088] Intravenous catheters, normally the catheter over needle type, are often used instead of intravenous needles for the injection of drugs because a sharp needle left in a vein can easily penetrate outside the wall of the vein if the patient moves his or her limb. However, because an energy assisted needle can be a relatively poor cutter when there is no energy applied, energy assisted needles could replace catheters in many applications. This has the benefit that for a given outside diameter and pressure capability, an energy assisted needle can have a larger inside diameter than a soft plastic catheter.

[0089] Alternatively, the needle in the normal catheter over needle design could be given an energy assist to make penetration of the vein easier and eliminate the problem of the vein moving out of the way.

[0090] A third option is to use the energy assisted needle to improve the needle over catheter design. The normal needle over catheter has a catheter inside a needle, and after penetrating the vein wall, the catheter is pushed forward into the vein and the needle is withdrawn back the shaft of the catheter. The needle is then split from around the catheter along a thinned lateral line. Energy assisted cutting could be advantageously used with these current needles. In addition, if a single or dual effector energy assisted needle were used, the needle need not be a full cylinder, but could just encompass the catheter for somewhat more than half a circle, more than 180 degrees. The assembly could be similar to that of Figure 3 where effector 121 is the plastic catheter, effector 122 is metal, and the other effectors are absent. To insert the IV catheter, a device similar to that of Figure 8 energizes the needle. After the vessel wall is pierced, the needle is slid back and the catheter is simply pulled from the needle. There is no need to split the needle. The flexibility in the plastic enables it to be pulled from the needle's grip. This embodiment has the benefit that the catheter does not have to have an end hole. It can, for example have many side holes or slits to disperse the fluid being injected and to avoid a jetting effect that can damage the vessel wall.

[0091] In IV catheter embodiments of the present invention, the forward end of the effector or the effector tip can, for example, be similar to that of effectors 102 and 103. The effector tip can have a macroscopic bevel as current needles. In certain embodiment, in can be preferable that the energy assisted cutting action take place only in a region +/- approximately 45

degrees to +/- approximately 90 degrees from the beveled tip. This region of cutting action facilitates the location of the cutting region of the needle against the center of the vein to be penetrated and reduces the chance of coring.

[0092] Although the present invention has been described in detail in connection with the above embodiments and/or examples, it should be understood that such detail is illustrative and not restrictive, and that those skilled in the art can make variations without departing from the invention. The scope of the invention is indicated by the following claims rather than by the foregoing description. All changes and variations that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

WHAT IS CLAIMED IS:

1. A device for penetrating tissue and removing a biological sample, comprising:

a biological sampling element to remove the biological sample, the biological sampling element including a passage therethrough; and

a penetrator positioned within the passage, the penetrator being energized in a repetitive manner to assist in penetrating tissue.

2. The device of claim 1 wherein the penetrator is energized continuously to assist in penetrating tissue.

3. The device of claim 1 wherein the penetrator is energized for discrete periods of time.

4. The device of claim 1 wherein the penetrator is energized in a manner to cause motion of the penetrator.

5. The device of claim 1 wherein the penetrator is energized to cause heating of the penetrator.

6. The device of claim 4 wherein the motion of the penetrator includes at least one of rotational motion or axial motion.

7. The device of claim 4 wherein the penetrator includes at least a single effector that is moved.

8. The device of claim 4 wherein the penetrator includes a plurality of effectors, at least one of which is moved.

9. The device of claim 4 wherein the penetrator comprises at least two effectors in close proximity to each other, relative motion between the two effectors assisting

penetration of tissue via interaction with tissue in regions where there is close proximity of tissue to an interface between the two effectors.

10. The device of claim 4 wherein the penetrator includes at least two effectors, including a first effector which is moved and a second effector in proximity to the first effector which is stationary, the first effector and the second effector cooperating to penetrated tissue via interaction with tissue in regions where there is close proximity of tissue to an interface between the first effector and the second effector.

11. The device of claim 4 wherein the penetrator includes at least two effectors, including a first effector which is moved and a second effector in proximity to the first effector which is also moved, the first effector and the second effector cooperating to penetrate tissue via interaction with tissue in regions where there is close proximity of tissue to an interface between the first effector and the second effector.

12. The device of claim 1 wherein the biological sampling element comprises:

a first tubular structure

a vibrational coupler that couples rotational energy into the first tubular structure, such that the vibrational energy cuts tissue at the leading edge of the first tubular structure;

a second tubular structure inside said first tubular structure such that the cut tissue inside the second tubular structure is protected from the effect of the rotational energy of the first tubular structure, the penetrator passing through the second tubular structure.

13. The device of claim 1 wherein the biological sampling element is adapted to remove a tissue sample.

14. The device of claim 13 wherein the biological sampling element is adapted to cut tissue and remove the tissue sample.

15. The device of claim 1 where in biological sampling element is adapted to remove a sample of biological fluid.

16. The device of claim 15 wherein the biological fluid is blood.

17. The device of claim 1 wherein electrical energy is used in energizing the penetrator.

18. A device for penetrating tissue and positioning a catheter, comprising:

a catheter comprising a passage therethrough; and

a penetrator in operative connection with the catheter, the penetrator being energized in a repetitive manner to assist in penetrating tissue.

19. The device of claim 18 wherein the penetrator is removably positioned within the passage of the catheter.

20. The device of claim 18 wherein the penetrator is positioned on the exterior of the catheter.

21. A needle for penetrating tissue comprising:

a first effector comprising a surface;

a second effector comprising a surface, the surface of the second effector being in close proximity to the surface of the first effector; and

at least one actuator in operative connection with one of the first effector and the second effector, the actuator adapted to cause relative motion between the first effector and the second effectors such that tissue penetration takes place in regions where there is close proximity of tissue to an interface between the first effector and the second effector.

22. A needle for sampling tissue, comprising

a first tubular structure;

a vibrational coupler that couples rotational energy into the first tubular structure, the vibrational energy being suitable to penetrate tissue at the leading edge of the first tubular structure;

a second tubular structure positioned inside the first tubular structure, such that cut tissue passes into the second tubular structure and is protected from the effect of the rotational energy of the first tubular structure.

23. A needle for penetrating tissue comprising:

a first effector in proximity to the distal end of the needle; and at least one actuator in operative connection with the first effector to energize the first effector to assist in penetrating tissue.

24. A needle system comprising:

a needle in operative connection with a syringe; and

an actuator in operative connection with the needle, the actuator adapted to energize to the needle to assist in penetrating tissue.

25. The needle system of claim 19 wherein the needle is connected to the syringe by a hub, the hub allowing relative motion between the needle and the syringe.

26. The needle system of claim 25 wherein the needle and the syringe are energized.

27. The needle system of claim 25 wherein the actuator is in operative connection with a cradle in which a needle and syringe are insertable to energize the needle.

28. A method of inserting a needle into tissue, comprising the step:

energizing at least a forward end of the needle to assist in penetrating tissue.

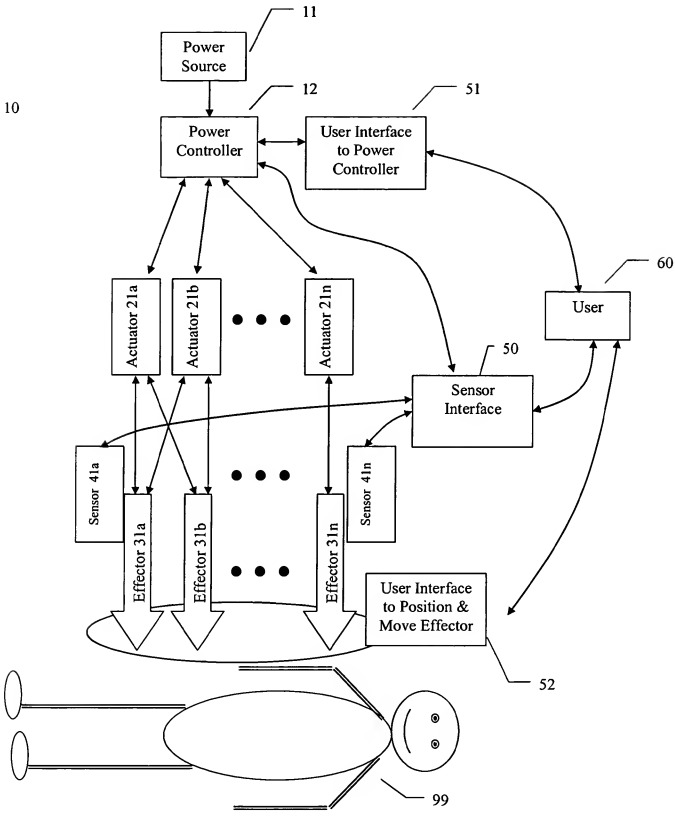
29. A method of inserting a catheter into tissue, comprising the step:

energizing an effector positioned at a forward end of the a catheter insertion device to assist in penetrating tissue.

ABSTRACT OF THE DISCLOSURE

A device for penetrating tissue and removing a biological sample includes a biological sampling element to remove a biological sample. The biological sampling element includes a passage therethrough. The device further includes a penetrator positioned within the passage. The penetrator is energized in a repetitive manner to assist in penetrating tissue. The biological sample element can be adapted to remove a tissue sample or a biological fluid sample (for example, blood).

Figure 1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Power Source
10
12
51
Power Controller
User Interface to Power Controller
60
User
Actuator 21a
Actuator 21b
Actuator 21n
50
Sensor Interface
Sensor 41a
Sensor 41n
Effector 31a
Effector 31b
Effector 31n
User Interface to Position & Move Effector
52
99

Figure 2

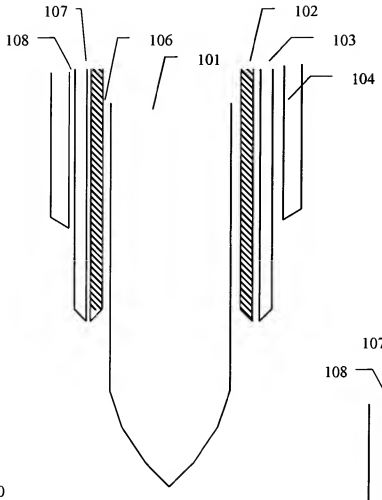

Figure 3

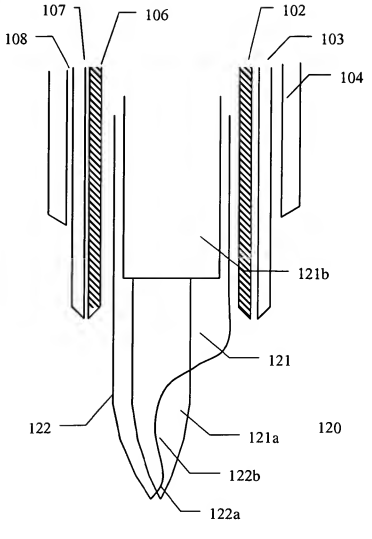

Figure 4

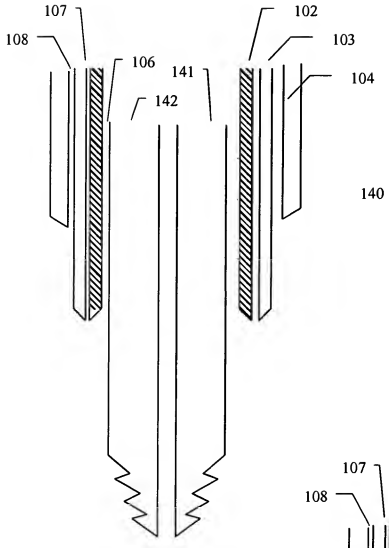

Figure 5

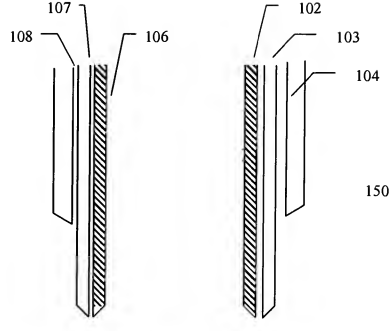

Figure 6

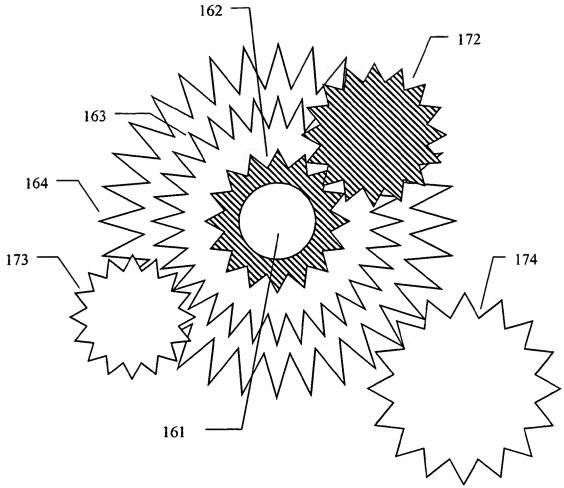

Figure 7

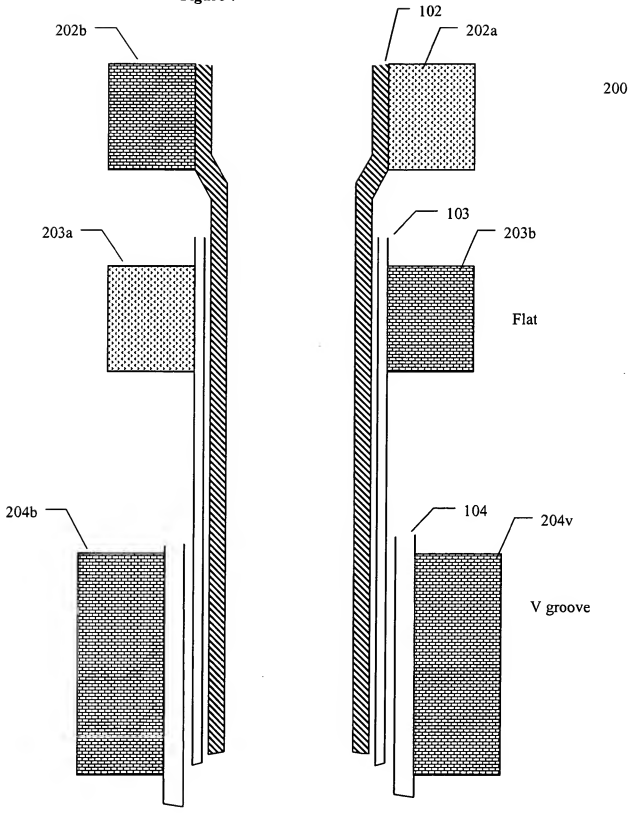

Figure 8